

10/532201

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: UMD-0097

Inventors: Mandola et al.

Serial No.: Not Yet Assigned

Filing Date: Herewith

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Title: Thymidylate Synthase Polymorphisms for  
Use in Screening for Cancer  
Susceptibility

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By Jane Massey Licata  
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Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information  
Disclosure Statement is being filed either within three

months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

( ) Certification in Accordance with §1.97(e) is attached hereto; or

( ) Authorization to charge Deposit Account No. 50-1619 the fee of \$180.00 as set forth in §1.17(p) is provided.

( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I) (1) .

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,



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Date: April 15, 2005

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<b>Form PTO-1449 Modified</b> List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce	Docket No. UMD-0097	Serial No. <b>10/532201</b> Not Yet Assigned
	Applicant Mandola et al.	
	Filing Date Herewith	Group Not Yet Assigned

## U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	AA	6,087,486	6-11-00	Weiner et al.	536	23.5

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	NO

EXAMINER	DATE CONSIDERED
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<b>Form PTO-1449 Modified</b>  List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce	Docket No. <b>UMD-0097</b>	Serial No. <b>49/532201</b> Not Yet Assigned
	Applicant <b>Mandola et al.</b>	
	Filing Date <b>Herewith</b>	Group <b>Not Yet Assigned</b>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	BA	Castelao et al., "Gender-and Smoking-Related Bladder Cancer Risk", Journal of the National Cancer Institute 2001 93(7):538-545
	BB	Chen et al., "A novel polymorphism in the thymidylate synthase gene promoter influences plasma folate level and may modify the risk of colorectal cancer in a prospective study", Proceedings from the American Association for Cancer Research 2002 43:page 659, Abstract #3272
	BC	Cok et al., "The 3'-Untranslated Region of Murine Cyclooxygenase-2 Contains Multiple Regulatory Elements That Alter Message Stability and Translational Efficiency", J. Biol. Chem. 2001 276(25):23179-23185
	BD	Galibert et al., "The Usf-1 transcription factor is a novel target for the stress-responsive p38 kinase and mediates UV-induced Tyrosinase expression", The EMBO Journal 2001 20(17):5022-5031
	BE	Giles et al., "The 3'-Untranslated Region of p21 <sup>WAF1</sup> mRNA Is a Composite cis-Acting Sequence bound by RNA-binding Proteins from Breast Cancer Cells, Including HuR and Poly(C)-binding Protein", J. Biol. Chem. 2003 278(5):2937-2946
	BF	Goto et al., "A Novel Single-Nucleotide Polymorphism in the 3'-Untranslated Region of the Human Dihydrofolate Reductase Gene with Enhanced Expression <sup>1</sup> ", Clinical Cancer Research 2001 7:1952-1956
	BG	Grzybowska et al., "Breakthroughs and Views - Regulatory Functions of 3'UTRs", Biochemical and Biophysical Research Communications 2001 288:291-295
	BH	Iacopetta et al., "A polymorphism in the enhancer region of the thymidylate synthase promoter influences the survival of colorectal cancer patients treated with 5-fluorouracil", British Journal of Cancer 2001 85(6):827-830
	BI	Ishida et al., "Association of Thymidylate Synthase Gene Polymorphism with its mRNA and Protein Expression and with Prognosis in Gastric Cancer", Anticancer Research 2002 22:2805-2810
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	BJ	Jaiswal et al., "Upstream Stimulating Factor-1 (USF1) and USF2 Bind to and Activate the Promoter of the Adenomatous Polyposis Coli (APC) Tumor Suppressor Gene", Journal of Cellular Biochemistry 2001 81:262-277
	BK	Kawakami et al., "Different Lengths of a Polymorphic Repeat Sequence in the Thymidylate Synthase Gene Affect Translational Efficiency but Not Its Gene Expression", Clinical Cancer Research 2001 7:4096-4101
	BL	Kawakami et al., "Identification and Functional Analysis of Single Nucleotide Polymorphism in the Tandem Repeat Sequence of Thymidylate Synthase Gene <sup>1</sup> ", Cancer Research 2003 63:6004-6007
	BM	Krajinovic et al., "Polymorphism of the thymidylate synthase gene and outcome of acute lymphoblastic leukaemia", The Lancet 2002 359:1033-1034
	BN	Luo et al., "Antiproliferative properties of the USF family of helix-loop-helix transcription factors", Proc. Natl. Acad. Sci. USA 1996 93:1308-1313
	BO	Mandola et al., "A Novel Single Nucleotide Polymorphism within the 5' Tandem Repeat Polymorphism of the Thymidylate Synthase Gene Abolishes USF-1 Binding and Alters Transcriptional Activity", Cancer Research 2003 63:2898-2904
	BP	Marsh et al., "Ethnic Variation in the Thymidylate Synthase Enhancer Region Polymorphism among Caucasian and Asian Populations", Genomics 1999 58:310-312
	BQ	Marsh et al., "The Thymidylate Synthase enhancer region polymorphism in colorectal cancer", Proceedings of the American Association for Cancer Research 1998 39:page 434, Abstract #2955
	BR	Marsh et al., "Novel Thymidylate Synthase Enhancer Region Alleles in African Populations", Human Mutation Mutation in Brief 2000 #376 1-6

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Form PTO-1449 Modified		Docket No. UMD-0097	Serial No. <b>107532201</b> Not Yet Assigned
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant <b>Mandola et al.</b>	
		Filing Date Herewith	Group Not Yet Assigned
U.S. Department of Commerce			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	BS	Matsukawa et al., "Up-Regulation of Upstream Stimulatory Factors by Protein Malnutrition and Its Possible Role in Regulation of the IGF-Binding Protein-1 Gene", Endocrinology 2001 142(11):4643-4651	
	BT	Nozoe et al., "Significance of Preoperative Elevation of Serum C-Reactive Protein as an Indicator for Prognosis in Colorectal Cancer", American Journal of Surgery 1998 176:335-338	
	BU	Nozoe et al., "Significance of preoperative elevation of serum C-reactive protein as an indicator of prognosis in esophageal carcinoma", American Journal of Surgery 2001 182:197-201	
	BV	Papamichael D., "The Use of Thymidylate Synthase Inhibitors in the Treatment of Advanced Colorectal Cancer:Current Status", The Oncologist 1999 4:478-487	
	BW	Skibola et al., "Polymorphisms in the thymidylate synthase and serine hydroxymethyltransferase genes and risk of adult acute lymphocytic leukemia", Blood 2002 99(10):3786-3791	
	BX	Trinh et al., "Thymidylate synthase:a novel genetic determinant of plasma homocysteine and folate levels", Hum Genet 2002 111:299-302	
	BY	Tsuji et al., "Polymorphism in the thymidylate Synthase Promoter Enhancer Region Is Not an Efficacious Marker for Tumor Sensitivity to 5-Fluorouracil-based Oral Adjuvant Chemotherapy in Colorectal Cancer", Clinical Cancer Research 2003 9:3700-3704	
	BZ	Ulrich et al., "Searching Expressed Sequence Tag Databases:Discovery and Confirmation of a Common Polymorphism in the Thymidylate Synthase Gene <sup>1</sup> ", Cancer Epidemiology, Biomarkers & Prevention, 2000 9:1381-1385	
	CA	Ulrich et al., "Thymidylate Synthase Promoter Polymorphism,Interaction with Folate Intake, and Risk of Colorectal Adenomas", Cancer Research 2002 62:3361-3364	
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	CB	Vilafranca et al., "Polymorphisms of the Repeated Sequences in the Enhancer Region of the Thymidylate Synthase Gene Promoter May Predict Downstaging After Preoperative Chemoradiation in Rectal Cancer", J. Clinical Oncology 2001 19(6):1779-1786	
	CC	Viollet et al., "Immunochemical Characterization and Transacting Properties of Upstream Stimulatory Factor Isoforms", J. Biol. Chem. 1996 271(3):1405-1415	
	CD	Wingender et al., "TRANSFAC:an integrated system for gene expression regulation", Nucleic Acids Research 2000 28(1):316-319	
	CE	Xiao et al., "Role of USF1 phosphorylation on cardiac $\alpha$ -myosin heavy chain promoter activity", Am J. Physiol Heart Circ Physiol 2002 283:H213-H219	
	CF	Database NCBI, Accession No. AF279906 [gi:12802218] 14 February 2001	
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